

Docket No. AB-147U

Remarks

Applicants acknowledge and appreciate the Examiner's indication that claims 9, 14, 17, 18, 20, 21, 23, 26, 27 and 29 contain allowable subject matter. By way of the present amendment, applicants have canceled claims 1, 4, 15 and 24; amended claims 2, 3, 13, 16, 17, 19, 22 and 25-29; and added new claims 30-32. Twenty-eight (28) claims remain pending in the application, claims 2, 3, 5-14, 16-23 and 25-32, of which claims 2, 3, 5, 8, 17, 26, 27, 28 and 29 are independent. Applicants respectfully request reconsideration of the pending claims, in view of the amendments above and comments below.

Allowable Subject Matter

Applicants acknowledge with appreciation that, in paragraph 7 of the Office action mailed March 01, 2004, the Examiner indicated that claims 9, 14, 17, 18, 20, 21, 23, 26, 27 and 29 contain allowable subject matter. These claims were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. As seen from the amendments *supra*, applicants have rewritten claims 17, 26, 27 and 29 as suggested. Claims 18, 20, 21 and 23 were already and remain dependent from claim 17, so are allowable based on the allowability of rewritten claim 17.

Claim Rejections - 35 U.S.C. § 112

In paragraphs 1 and 2 of the Office action mailed March 01, 2004, claims 13, 19 and 22 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

Application No. 09/993,084
Amendment A dated July 01, 2004
Reply to Office Action dated March 01, 2004

Page 8 of 16

Docket No. AB-147U

particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner stated that

the language "greater than about 50-100 Hz" and "less than about 50-100 Hz" is unclear.

While not agreeing that this language is unclear, applicants have amended claims 13, 19 and 22 as such amendment arguably broadens coverage of these claims, and certainly does not narrow these claims.

Claim Rejections - 35 U.S.C. § 102

In paragraphs 3, 4 and 5 of the Office action, claims 1-8, 10-13, 15 and 16 were rejected under 35 U.S.C. 102(e) as being clearly anticipated by WO 01/66183 A1 ('183 application).

By way of the present amendment, claims 1, 4 and 15 have been canceled, rendering this rejection moot therefor.

Claims 2 and 3 have been amended to incorporate all the limitations of claim 1, from which they depended.

Regarding claim 2, applicants submit that the '183 application fails to show "applying...stimulus...to hyperpolarize...an alpha cell...wherein the hyperpolarization inhibits secretion of glucagon."

- First, while the '183 application mentions controlling glucagon secretion (e.g., page 3, lines 14-15; page 4, lines 13 and 19; page 14, lines 5-6; page 23, lines 29-30; page 28, line 34 and Fig. 3B, claims 7-10) it fails to teach *how* to use an electrode to control glucagon secretion, and certainly does not describe "hyperpolariz[ing]...an alpha cell...[to] inhibit[] secretion of glucagon."

Application No. 09/993,084
Amendment A dated July 01, 2004
Reply to Office Action dated March 01, 2004

Page 9 of 16

Docket No. AB-147U

- Second, any hyperpolarization taught in the '183 application applies to "hyperpolarization of beta cells" (e.g., page 2, line 10; page 20, lines 3-6; page 21, line 29; page 22, lines 21-22), not hyperpolarization of alpha cells.
- Third, the '183 application actually *teaches away* from interacting with "non-beta cells" such as alpha cells. See page 34, lines 1-4:

Alternatively or additionally, the application of stimulation in general may be optimized to reduce interaction with non-beta cells, for example alpha cells. As alpha cells generate glucagon, their stimulation may be determined by tracking serum glucagon levels.

The '183 application teaches "tracking serum glucagon levels" to ensure alpha cells are *not* stimulated. This *teaches away* from the invention of claim 2.

It is respectfully submitted that a fundamental requirement of a claim rejection under 35 U.S.C. 102(e) is that every element of the claimed invention must be identically shown in a single reference. In view of the above, applicants submit that every element of now-independent claim 2, especially applying stimulus to hyperpolarize an alpha cell wherein the hyperpolarization inhibits secretion of glucagon, is not singularly disclosed in the '183 application. Thus, applicants respectfully assert based on the foregoing that amended claim 2 is in condition for allowance. Acknowledgment of the same is earnestly solicited.

Similarly, regarding claim 3, applicants submit that the '183 application fails to show "applying...stimulus...to hyperpolarize...a delta cell...wherein the hyperpolarization inhibits secretion of somatostatin."

- First, while the '183 application mentions controlling somatostatin secretion (e.g., page 3, line 30; page 14, lines 8-9; page 23, lines 29-30; claim 11) it fails to teach

Docket No. AB-147U

how to use an electrode to control somatostatin secretion, and certainly does not describe "hyperpolariz[ing]...a delta cell...[to] inhibit[] secretion of somatostatin."

- Second, as stated above, any hyperpolarization taught in the '183 application applies to "hyper-polarization of beta cells" (e.g., page 2, line 10; page 20, lines 3-6; page 21, line 29; page 22, lines 21-22), not hyperpolarization of delta cells.
- Third, the '183 application actually teaches away from interacting with "non-beta cells" such as delta cells. See page 34, lines 1-4:

Alternatively or additionally, the application of stimulation in general may be optimized to reduce interaction with non-beta cells, for example alpha cells.

- The '183 application teaches *reducing* interaction with non-beta cells. This teaches away from "applying...stimulus...to hyperpolarize...a delta cell" as claimed in claim 3.

In view of the above, applicants submit that every element of now-independent claim 3, especially applying stimulus to hyperpolarize a delta cell wherein the hyperpolarization inhibits secretion of somatostatin, is not singularly disclosed in the '183 application. Thus, applicants respectfully assert based on the foregoing response that amended claim 3 is in condition for allowance. Acknowledgment of the same is earnestly solicited.

Regarding claim 5, applicants also submit that the '183 application fails to show "applying...stimulus...to depolarize...[a] pancreatic cell to...increase secretion of a substance that inhibits insulin secretion." The '183 application teaches depolarization for two purposes:

- 1) to cause insulin secretion: the '183 application uses depolarization of pancreatic beta cells to increase calcium in the cells, which in turn causes the cells to "yield their

Docket No. AB-147U

stores of insulin" (e.g., page 9, lines 16-17; page 11, line 22 - page 12, line 8; page 19, lines 23-31; page 20, lines 5-8, 17-19 and 26; page 21, lines 5-9; page 26, lines 31-33), and

- 2) to synchronize action potentials of multiple cells (e.g., see page 12, lines 17-19; page 21, lines 10-15).

The methods of inhibiting insulin secretion that are described in the '183 application (page 21, line 22 - page 22, line 15) do not include "applying...stimulus...to depolarize...[a] pancreatic cell to...increase secretion of a substance that inhibits insulin secretion" as claim 5 requires. As every element of independent claim 5 is not identically disclosed in the '183 application, applicants respectfully request reconsideration and withdrawal of the rejection of claim 5.

Claims 6 and 7 also stand rejected as being anticipated by the '183 application. Since these claims depend directly from independent claim 5 (allowable based on the aforementioned remarks) and further limit the claim from which they depend, claims 6 and 7 should also be allowable. Applicants respectfully request acknowledgment of the same.

Regarding claim 8, applicants have carefully reviewed the '183 application and can find no mention of "applying stimulation to...at least one parasympathetic tissue" as required by the claim. In addition, there is no teaching to use parasympathetic tissue stimulation "in order to minimize stimulation of gastrointestinal structures and the heart while maximizing stimulation of pancreatic beta cells" as required by claim 8. While the '183 application mentions "nervous stimulation", none of these refers to parasympathetic tissue stimulation. For example:

Application No. 09/993,084
Amendment A dated July 01, 2004
Reply to Office Action dated March 01, 2004

Page 12 of 16

Docket No. AB-147U

- 1) Page 2, lines 13-20, in the background section of the '183 application, describe a prior art publication. The publication is characterized as including a description of "an experiment in which sympathetic nervous stimulation caused an increase in Somatostatin secretion." This sympathetic stimulation is clearly not relevant to the parasympathetic stimulation of claim 8, but is relevant to other claims discussed in more detail below.
- 2) Page 3, lines 10-13 describe the "lack of success of nervous or direct stimulation of the pancreas for glucose control." This actually *teaches away* from the parasympathetic tissue stimulation of claim 8.
- 3) Page 5, lines 1-11 mentions "nervous stimulation" (line 11) as part of "mapping the response and/or feedback behavior of a pancreas" and more particularly, used to determine "response of hormone secretion and/or production to various stimulatory and inhibitory effects." Thus, this stimulation is used for sensing response, and is not stimulation of parasympathetic tissue "to minimize stimulation of gastrointestinal structures and the heart while maximizing stimulation of pancreatic beta cells" as required by claim 8.

In view of the above, applicants submit that every element of independent claim 8, especially applying stimulation to parasympathetic tissue in order to minimize stimulation of gastrointestinal structures and the heart while maximizing stimulation of pancreatic beta cells, is not singularly disclosed in the '183 application. Thus, applicants respectfully assert based on the foregoing response that amended claim 8 is in condition for allowance. Acknowledgment of the same is earnestly solicited.

Docket No. AB-147U

Claims 10-13 also stand rejected as being anticipated by the '183 application. Since these claims depend directly from independent claim 8 (allowable based on the aforementioned remarks) and further limit the claim from which they depend, claims 10-13 should also be allowable. Applicants respectfully request acknowledgment of the same.

Claims 15 and 16 were also rejected as being anticipated by the '183 application. As claim 15 has been canceled by the present amendment, the rejection of claim 15 is now moot. Claim 16, which depended from claim 15 has been amended to depend from **claim 17**, which was considered by the Examiner to be "allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Claim 17 has been so amended. **Claims 18-23** depend, directly or indirectly from now-independent claim 17, so should also be allowable. Applicants respectfully request acknowledgment of the same.

In paragraph 6 of the Office action mailed March 01, 2004, **claims 24, 25, and 28** were rejected under 35 U.S.C. 102(e) as being anticipated by Houben et al '141 (US 2002/0026141 A1). As claim 24 has been canceled by the present amendment, the rejection of claim 24 is now moot. Claim 25, which depended from claim 24 has been amended to depend from **claim 26**, which was considered by the Examiner to be "allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Claim 26 has been amended, is now in independent form, and is believed to be allowable.

Docket No. AB-147U

Regarding claim 28, the Office action states that:

Houben et al disclose applying drug stimulation comprising delivering insulin.
It is well known, insulin stimulates the secretion of glucagon.

Yet, claim 28 does not include "applying drug stimulation comprising delivering insulin."

Claim 28 includes drug stimulation via "at least one of an alpha-adrenergic agonist, arginine, and alanine." Furthermore, the present invention claims insulin use to *inhibit* glucagon secretion (see claim 29). In view of the above, applicants submit that every element of now-independent claim 28 (which was rewritten in independent form including all of the limitations of the base claim and any intervening claims) is not singularly disclosed in Houben et al. Thus, applicants respectfully assert based on the foregoing that amended claim 28 is in condition for allowance. Acknowledgment of the same is earnestly solicited.

Claims 27 and 29 were considered by the Examiner to be "allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Claims 27 and 29 have been amended, are now in independent form, and are believed to be allowable.

New Claims

New dependent claims 30-32 are modeled after originally-filed dependent claim 25 and depend from claims 27-29, respectively, so should also be allowable. Applicants respectfully request acknowledgment of the same.

Application No. 09/993,084
Amendment A dated July 01, 2004
Reply to Office Action dated March 01, 2004

Page 15 of 16

Docket No. AB-147U

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and the pending claims are in condition for allowance. An indication of allowability of claims, claims 2, 3, 5-14, 16-23 and 25-32, at an early date is earnestly solicited.

The Examiner is invited to telephone the undersigned, Laura Bishop, at his convenience should any issues remain after consideration and entry of this response, in order to permit early resolution of the same.

Respectfully Submitted,

Date

2004 July 01Laura Haburay Bishop
Laura Haburay Bishop
Reg. No. 47,424Address all correspondence to:

Bryant R. Gold
Advanced Bionics Corporation
25129 Rye Canyon Rd.
Valencia, CA 91355
Fax: (661) 362-1507 or (760) 788-9629

Direct telephone inquiries to:

Laura Haburay Bishop
Phone: (661) 362-1906
Fax: (661) 362-1507

Application No. 09/993,084
Amendment A dated July 01, 2004
Reply to Office Action dated March 01, 2004

Page 16 of 16